

REMARKS

Claims 21-52 are currently pending in the application and stand rejected. Claims 1-20 have been previously canceled. Claims 24, 31, 38 and 43 have been canceled, Claims 21, 28, 30, 32, 39, 40, 44, 45 and 50 have been amended and Claims 53 and 54 have been added herein. Claims 21-23, 25-30, 32-37, 39-42 and 44-54 are now pending in the application. Support for the amendments and new claims can be found throughout the application, drawings and claims as originally filed and, as such, no new matter has been presented. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments, new claims and remarks contained herein.

REJECTION UNDER 35 U.S.C. §§ 102 AND 103

Claims 21-25, 27-34 and 48-50 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Romano (U.S. Pat. No. 5,002,546; hereinafter "Romano"). Claims 26 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Romano. Claims 39-45, 51 and 52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Romano in view of Fukuda (U.S. Pat. No. 4,345,601; hereinafter "Fukuda"). These rejections are respectfully traversed.

Romano discloses a curved bore drilling apparatus 20, which includes a rocker arm 24 secured to a housing 36, a curved guide means 26 and a cutting means 28. The rocker arm 24 is coupled to the curved guide means 26. The rocker arm 24 is pivotable to move the curved guide means 26. The rocker arm 24 and curved guide means 26 can be formed from a single piece of material. Note that the curved guide means 26 is formed into a bent shape to define a predetermined curved path. Thus, the

curved guide means 26 of Romano is rigid, and is not flexible. The curved guide means 26 also defines a channel 65, which can receive the cutting means 28. The cutting means 28 can be guided along the predetermined path defined by the curved guide means 26. Thus, when the rocker arm 24 pivots, the curved guide means 26 coupled to the rocker arm 24 can move outwardly, and thereby guide the cutting means 28 along the predetermined path defined by the curved guide means 26.

Fukuda discloses a continuous suturing device that includes a needle 11. A suture can be coupled to the needle 11 via a needle cap 13. The needle cap 13 is held on the end of the needle 11 through frictional engagement.

In contrast to the cited art, independent Claim 21 recites:

...guiding the flexible single shaft cutting tool with the **flexible** guide mechanism from the first bone location to a second bone location;...

associating a **suture engaging hook** with the flexible single shaft cutting tool;

engaging a suture with the suture engaging hook at the second bone location; and

pulling the suture through the non-linear path from the second bone location to the first bone location to secure the suture to a selected tissue near to the first and second bone location after the non-linear path has been formed (emphasis added).

Independent Claim 28 recites:

...guiding the drill head with the flexible drill shaft with a guide mechanism along a selected non-linear cutting path within the bone structure by:

positioning at least a portion of the flexible drill shaft **through a flexible rod**;

connecting a **flexible member** to a portion of the flexible drill shaft;

sliding a handle to tension the flexible member to assist in directing the flexible drill shaft along the selected non-linear path; and... (emphasis added).

Independent Claim 39 recites:

...guiding the drill head and flexible drill shaft with a **flexible guide mechanism** through an entry position and through the identified bone structure in a first direction, by:
engaging a **flexible rod** with a housing with the flexible drill shaft;
coupling the flexible drill shaft to the flexible rod at a proximal end;
engaging a handle with a distal end of the flexible rod and the housing;
manipulating the handle to direct the flexible drill shaft along a **non-predetermined path**;... (emphasis added).

Rather, Romano discloses the use of a rigid curved guide means 26, and not the use of a flexible guide mechanism or a flexible single shaft cutting tool including associating a suture engaging hook with the flexible single shaft cutting tool and engaging a suture with a suture engaging hook... and pulling the suture through a nonlinear path, as claimed in claim 21. Further, Romano discloses that the curved guide means 26 defines a channel, but does not disclose the use of positioning at least a portion of a flexible drill shaft through a flexible rod, connecting a flexible member to a portion of the flexible drill shaft, and sliding a handle to tension the flexible member to assist in directing the flexible drill shaft along a selected nonlinear path, as claimed in claim 28. With regard to claim 39, neither Romano nor Fukuda either singly or in combination discloses engaging a flexible rod with a housing with a flexible drill shaft, coupling the flexible drill shaft to the flexible rod..., engaging a handle with the distal end of the flexible rod and the housing, and manipulating the handle to direct the flexible drill shaft along a non-predetermined path.

Accordingly, in view of at least the above discussion, Applicants respectfully submit that the cited art does not teach, suggest or disclose each and every element of independent Claims 21, 28 and 39, and thus, Applicants respectfully request the Office to reconsider and withdraw the rejection of independent Claims 21, 28 and 39 under 35 U.S.C. §§ 102(b) or 103(a).

In addition, since Claims 22, 23, 25-27, 29, 30, 32-35, 40-45 and 48-50 depend directly or indirectly from independent Claims 21, 28 or 39, Claims 22, 23, 25-27, 29, 30, 32-35, 40-45 and 48-50 should be in condition for allowance for at least the reasons set forth for Claims 21, 28 and 39, above. In addition, note that at least some of the dependent claims contain allowable subject matter. In this regard, note that the cited art does not teach, suggest or disclose interconnecting a flexible member to the flexible drill shaft, sliding the handle to cause tension in the flexible member to direct the flexible drill shaft along the first and second path while forming the tunnel, or wherein guiding the drill head includes changing a direction of the drill head after beginning forming the tunnel, as claimed in Claim 44. Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 22, 23, 25-27, 29, 30, 32-35, 40-45 and 48-50 under 35 U.S.C. §§ 102(b) or 103(a).

Claims 36-38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Romano further in view of Hyde (U.S. Pub. No. 2002/0095214; hereinafter "Hyde"). Claim 42 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari in view of Hyde and further in view of Moore et al. (U.S. Pat. No. 4,872,451; hereinafter "Moore"). Claims 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being

unpatentable over Romano in view of Fukuda further in view of Hyde. These rejections are respectfully traversed.

Since Claims 36-38, 42, 46 and 47, depend directly or indirectly from independent Claims 28 or 39, Claims 36-38, 42, 46 and 47 should be in condition for allowance for at least the reasons set forth for Claims 28 and 39, above. In addition, note that none of Hyde or Moore remedy the shortcomings of Romano, Fukuda and/or Harari as discussed above. Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 36-38, 42, 46 and 47 under 35 U.S.C. §103(a).

Claims 39-41 and 43-47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari et al. (U.S. Pat. No. 6,328,744) in view of Hyde. This rejection is respectfully traversed.

Harari discloses a bone boring device that includes rigid needles for boring through the bone. In Figs. 9A and 9B, Harari discloses that the boring device includes a needle 302 attached to a hinge via a needle arm 304. The needle 302 is rotatable to bore a curved channel through the bone. Harari discloses that the needles are pushed into the bone. In Figs. 17A-17B, Harari discloses two drill bits 504 coupled adjacent to needles 508, 520. The drill bits 504 are used to drill two linear apertures 540 in the bone, and the needles 508, 520 are used to form a curved bore 542 in the anatomy.

With regard to Hyde, note that Hyde discloses a transosseous core approach to access an articulating surface. Hyde teaches drilling a core through a first bone A with a non-articular surface 8A such that the core or bone hole CH1 is adjacent to an articular surface 1A of a second bone B. The drilling of the bone hole CH1 enables the

treatment of the articular surface 1A as tools can pass through the bone hole CH1. Hyde does not teach, suggest or disclose the use of any type of guide mechanism to form the bone hole CH1, let alone the use of a flexible guide mechanism. In contrast to the cited art, independent Claim 39 has been amended to recite:

...guiding the drill head and flexible drill shaft with a **flexible guide mechanism** through an entry position and through the identified bone structure in a first direction, by:

engaging a **flexible rod** with a housing with the flexible drill shaft;

coupling the flexible drill shaft to the flexible rod at a proximal end;

engaging a handle having a proximal end and a distal end with a distal end of the flexible rod and the housing;

manipulating the handle to direct the flexible drill shaft along a **non-predetermined path**;... (emphasis added).

In view of the above discussion, Applicants respectfully assert that the cited art does not teach, suggest or disclose each and every element of independent Claim 39. Rather, Harari teaches the use of rigid arcuate needles that are pushed into the bone and does not disclose whatsoever guiding the needles into the bone with a flexible guide mechanism, as claimed. Further, the needles of Harari form a predetermined path (i.e., the rigid arcuate needles form a path predetermined by the rigid shape of the needles). Hyde does not remedy this shortcoming of Harari. Hyde merely discloses the formation of one or more bone holes in an anatomy to reach an articular surface. In addition, Applicants note it is improper to modify Harari with Hyde as this modification would change the principle of operation of the bone boring system of Harari.

Accordingly, in view of at least the above discussion, Applicants respectfully submit that the cited art does not teach, suggest or disclose each and every element of independent Claim 39, and thus, Applicants respectfully request the Office to reconsider and withdraw the rejection of independent Claim 39 under 35 U.S.C. § 103(a). In addition, since Claims 40, 41 and 43-47 depend directly or indirectly from independent Claim 39, Claims 40, 41 and 43-47 should be in condition for allowance for at least the

reasons set forth for Claim 39, above. Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 40, 41 and 43-47 under 35 U.S.C. § 103(a).

NEW CLAIMS


Applicants have added new Claims 53 and 54. Applicants note that support for these claims can be found throughout the specification and drawings as originally filed, in at least paragraph [0031], and thus, these claims do not add new matter. In addition, it is believed these claims contain allowable subject matter as the cited art teaches away from the non-linear path being defined by more than a single radius as claimed in Claim 53, and from the non-linear path being a non-predetermined path as claimed in Claim 54. Prompt and favorable consideration of the new claims is hereby respectfully requested.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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